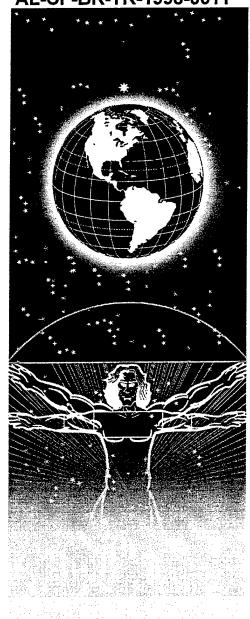
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UNITED STATES AIR FORCE ARMSTRONG LABORATORY

TESTING AND EVALUATION OF THE LIFEPORT, INC. LIFEPORT PATIENT LOADING UTILITY SYSTEM (PLUS)



Butch O. Blake

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May 1998

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Air Crews from 332 ALF/Randolph AFB

TESTING AND EVALUATION OF THE LIFEPORT, INC. LIFEPORT PATIENT LOADING UTILITY SYSTEM (PLUS)

BACKGROUND

Representatives of the LifePort company approached Aeromedical Research to evaluate and approve their product for use on board USAF aeromedical evacuation weapon systems. Specific components of the LifePort Patient Loading Utility System (PLUS) included the LifePort PLUS base unit, AeroSled Transport System (TS), Loading System with a load ramp, telescoping IV pole, suction canister, O2 flowmeter, AeroSled Arch and 28 VDC power cord. All components of the LifePort PLUS were tested for air worthiness. Throughout this report, the term Equipment Under Test (EUT) refers to the LifePort Patient Loading Utility System.

DESCRIPTION

The Six-foot EUT is composed of the following features: a 124 cu ft oxygen system with DISS or Ohio outlet which provides 3.8 hrs of O₂ at15 lpm; two 518 watt Inverters with one wired as a backup, and only one is operational at a time; a 28 VDC Vacuum System rated at 22 inHg with DISS or Ohio outlets; two 28 VDC Compressed Air Systems each achieving 100 psi and regulated to 50 psi to a DISS or Ohio outlet; Control Panel with three single AC electrical outlets and vacuum and air pressure gauges; remote O₂ fill port and quantity gauge; AeroSled Transport System (TS) with a pneumatically controlled backrest that adjusts from 0 - 60° to include a patient safety restraint system; high density foam pad and cover; Loading System with a load ramp that attaches to the EUT or a ramp bay and folds for storage; Externally attached telescoping IV pole; Suction canister; O₂ flowmeter; and External AeroSled Arch that connects over AeroSled TS used to mount life support equipment.

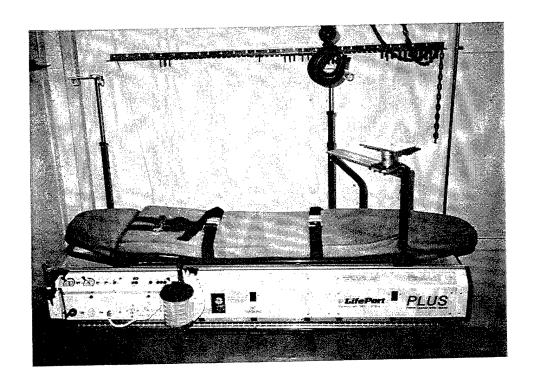


Figure 1. Lifeport, Inc., Patient Loading Utility System (PLUS).

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 5), military standards (2-4 & 6-8), and manufacturer's literature (9). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check were developed specific to this EUT to verify its proper functioning of the equipment under various testing conditions. Unless otherwise noted all testing is conducted and monitored by Aeromedical Research personnel assigned to the Systems Research Branch (CFTS), Crew Technology Division, Armstrong Laboratory, Brooks AFB, TX.

The EUT was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

- 1. Initial Inspection
- 2. Vibration
- 3. Electromagnetic Interference (EMI)

- 4. Thermal/Humidity Environmental Conditions, encompassing:
 - a. Hot Operation
 - b. Cold Operation
 - c. Humidity Operation
 - d. Hot Temperature Storage
 - e. Cold Temperature Storage
- 5. Hypobaric Conditions
 - a. Cabin Pressure/Altitude
 - b. Rapid Decompression to Ambient Pressure
- 6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

- a. The EUT was inspected for quality of workmanship, production techniques and preexisting damage.
- b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1), Electrical Shock Hazards, AFI 41-203 (2), and Equipment Management in Hospitals, AFI 41-201 (3).
- c. The EUT was examined to assess compliance with basic requirements for human factors design as outlined in MIL-STD 1472 (4).
- d. A test setup and performance check were developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The device will operate from two 28 VDC/25 Amp power supplies wired in parallel by way of a pigtail adapter provided by the manufacturer. Oxygen and air flowmeters are inserted into ports provided on the front control panel with Biometer DPM III pressure meters placed inline by way of a "T" adapter to varify system pressures. A continuous suction unit provided by

the manufacturer was inserted into the vacuum outlet to measure the amount of suction provided by the internal vacuum pump. Readings were taken manually from flowmeters, the provided continuous suction unit and the EUT's own gauges. Air flowmeters are set to 15 lpm and the continuous suction unit was set to maximum vacuum by Aeromedical Research personnel. To draw output amperage from the 115 VAC/60 Hz outlets two 250 watt bulbs were plugged into outlets on the unit to provide a continuous 4.3 amp load. (Figure 2)

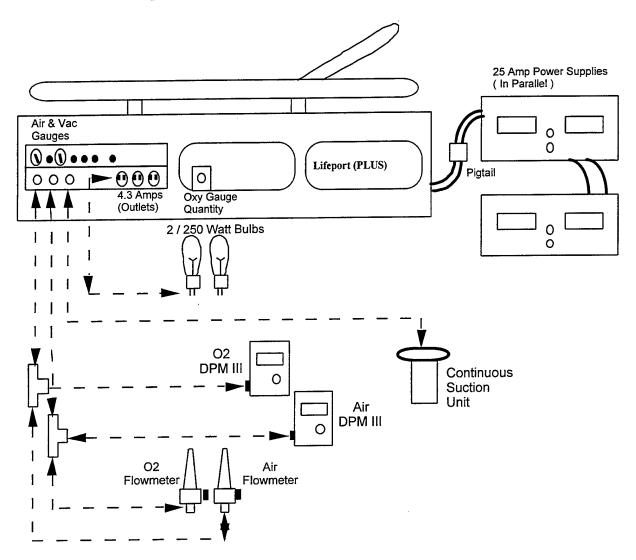


Figure 2. Lifeport Test Set-Up

PERFORMANCE CHECK

The measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. A baseline test consisted of powering the device using 28 VDC

power supplies to check the device's internal component readings against manufacture's and user demand specifications.

A performance check was performed and recorded before and after each laboratory test. During each laboratory test a complete test was done and the parameters recorded. Values derived from pretest recordings were used as a baseline reference in determining variation in results during each portion of testing. Post-performance check values were used to identify any deviation from the pre-performance check values which might indicate damage to the EUT's internal components as a result of testing.

VIBRATION

These tests are designed to determine an item's construction, durability, and performance during worst case scenario vibrations. The EUT was subjected to vibration curves with slightly modified levels and lengths from those depicted in Category 10, figures 514.4-16 and 514.4-17 of MIL-STD-810E (3) (Figure 4). Tests consist of random (11 to 2,000 Hz) and sinusoidal (5 to 500 Hz) curves on X, Y, and Z axies. During sinusoidal tests, the EUT was operated and vibrated for 5 sweeps of 15 minute duration (for a total of 75 minutes) on each axis. During random tests, the EUT was operated and vibrated for 30 minutes on each axis. Before and after each axis, a visual examination of the unit was performed and measurements were recorded.

During vibration testing the EUT was secured to the vibration table using the C-21A Learjet floor adapter specifically designed by the manufacturer simulating the floor of aircraft (Figure 3). The EUT was then subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

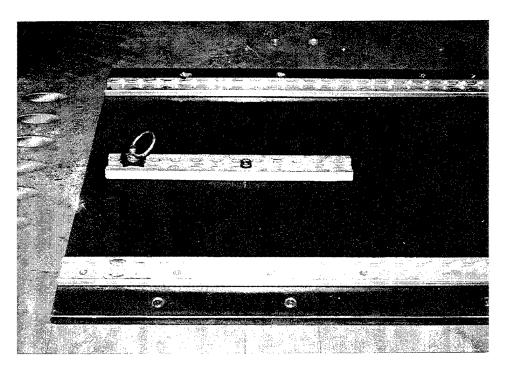
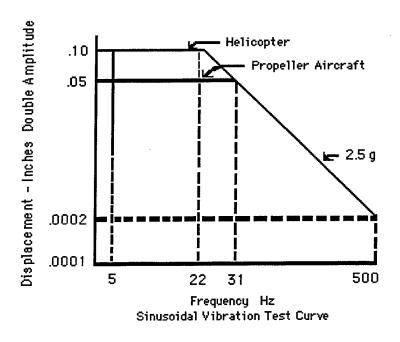


Figure 3. Manufacturer's Simulated Aircraft Floor.



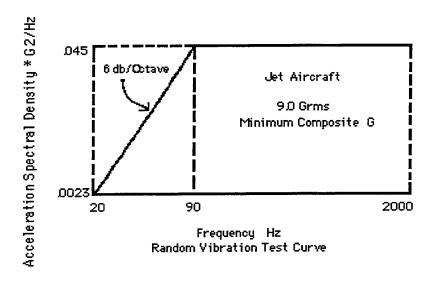


Figure 4. Category 10, figures 514.4-16 and 514.4-17 of MIL-STD-810E

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety of everyone on board is the driving factor to assessing the effects of excessive electromagnetic emissions and potential influence on aircraft navigation

and communications equipment. Medical devices may be susceptible to fields generated by the aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D and MIL-STD-462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

- a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz 1 GHz. This test measured the amount of EMI emitted by the EUT during operation. It verifies the EUT's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).
- b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz 10 MHz. This test measured emissions generated by the EUT along its power supply lines. It was performed to assess the device's potential to affect other items connected to the same power source, particularly aircraft systems.
- c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (field strength values from MIL-STD-461D Table IV, Category Aircraft Internal). This test evluated the EUT's resistence to predefined levels of EMI generated by antennas both internal and external to the aircraft.
- d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT's ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."
- e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the EUT."
- f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

g. Conducted Susceptibility (CS-116), "Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power Leads, 10 kHz - 100 MHz," respectively. The "basic concept of this test is to simulate electical current and volatge waveforms occurring in platforms from excitation of natural resonances."

During emissions testing, all EUT electrical components were operating for the duration of the test to create the worst case emissions scenario. In these tests, the EUT operated in the maximum vacuum mode. For susceptibility testing, the EUT was operated again in the maximum vacuum mode. For both emissions and susceptibility testing, the EUT was tested for operation on 115 VAC/60-400 Hz, and internal batteries.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions "without experiencing physical damage or deterioration in performance." (6) Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory's Thermotron Industries, model SM-32 environmental chamber. The EUT was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup remained outside the chamber. For operational tests, the EUT was monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT was placed in the chamber and remained nonoperational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

- a. Humidity Operation: $94 \pm 4\%$ RH, $85^{\circ}F \pm 3.6^{\circ}F$ ($29.5^{\circ}C \pm 2^{\circ}C$) for 4 hrs
- b. Hot Temp Operation: $120^{\circ}F \pm 3.6^{\circ}F$ ($49^{\circ}C \pm 2^{\circ}C$) for 2 hrs
- c. Cold Temp Operation: $32^{\circ}F \pm 7.2^{\circ}F$ ($0^{\circ}C \pm 4^{\circ}C$) for 2 hrs
- d. Hot Temp Storage: $140^{\circ}F \pm 3.6^{\circ}F$ ($60^{\circ}C \pm 2^{\circ}C$) for 6 hrs
- e. Cold Temp Storage: $-40^{\circ}F \pm 3.6^{\circ}F$ ($-40^{\circ}C \pm 2^{\circ}C$) for 6 hrs

HYPOBARIC CONDITIONS

Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operation personnel assigned to the Systems Research Branch (CFTS), Crew Technology Division, Armstrong Laboratory, Brooks AFB, TX.

- a. Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000 10,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 10,000 ft; stopping at 2,000 ft increments for performance checks; and then descending back to ground, at rates of 5,000 ft/min. Descent is stopped every 2,000 ft for performance checks.
- b. Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD so as not to endanger a patient, personnel, or the aircraft itself. The EUT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice more; once for a 7 second RD and once for a 1 second RD. The EUT was monitored throughout the series of decompressions; performance checks were assessed each time the unit returned to ground level.

AIRBORNE PERFORMANCE

Airborne feasibility evaluations are a cost-effective and invaluable means of validating a piece of equipment's clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their actual environment, Aeromedical Research ensures that all pertinent patient care issues are adequately addressed by the test protocols. Ensuring safe and reliable operation of this medical equipment support device is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by qualified aeromedical crew members from Aeromedical Research on C-21A Learjet. The EUT was positioned and secured to the aircraft floor and evaluated. Human factors characteristics, securing methods, and equipment setup/tear down times and securing locations were also evaluated. Feedback from other aeromedical evacuation crew members participating in delivery of patient care was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification.

VIBRATION

The EUT operated according to manufacturer's specifications. After analysis Aeromedical Research finds the unit acceptable for use in the aeromedical evacuation environment.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system on all U.S. Air Force aircraft while operating from 28 VDC power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

To pass the rigors of thermal & humidity the EUT was modified by the manufacturer to remove excess water build-up from the air system. The air pumps had to be reconfigured in parralell and a heat exchanger mounted on a muffin fan was installed due to a possible thermodynamics problem caused by air compressors close proximity to each other. After these modifications the EUT operated satisfactorily during all five phases of testing.

HYPOBARIC CONDITIONS

- 1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing.
- 2. Rapid Decompression: The EUT operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on a C-21A Learjet. Evaluation confirmed that the unit would operate successfully during all phases of flight. Analysis of flight data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems. It was also noted that the power cord length may not be sufficient when

securing the unit to the floor of the aircraft and may need to be lengthened to allow securing unit to the aircraft's floor.

This evaluation confirmed that the EUT will successfully function on the C-21 Learjet and is compatible with the electrical system. To operate the unit on other aeromedical evacuation aircraft specialized securing adapters are required. These adapters can be obtained through the manufacturer. During this evaluation the following was observed.

General observations:

- 1. Due to interior height restrictions on the C-21 aircraft, performing Cardiopulmonary Resuscitation (CPR) may prove difficult. Full arm extension is not possible when performing cardiac compressions.
- Exercise extreme caution when working within close proximity or
 passing in front of the base unit. There is a possibility of breaking or
 dislodging flowmeters, suction devices, and power cords from auxiliary life
 support equipment.
- 3. When using more than one EUT, space limitations will hamper accessibility to egress exits by medical crew.
- 4. Because of the close proximity of the C-21 aircraft's passenger seats, visualization of base units flowmeters and suction devices may be difficult.
- 5. Placement in the C-21A may require the EUT to be placed close to the rear bench seat, blocking space for medical attendants or ambulatory patients.
- 6. Exposed metal surfaces around air compressor compartment become very warm to touch; use extreme caution.

RECOMMENDATIONS

- 1. Head of bed control lever for raising and lowering patient's head should be located on both sides of the patient stretcher to allow convenient access.
- 2. Unit will require indoor storage due to exposed electrical outlets.
- 3. If used on C-9A aircraft, enplane/deplane unit using the patient ramp only. Using the Forward Crew entrance door or aft stairs could result in damage to the unit.
- 4. Gauges, flowmeters, and suction devices need to be closely monitored due to barometric pressure changes experienced during ascent and descent.
- 5. The Ohio Intermittent Suction Unit must be angled 45° to the right to allow connection into the outlet port on the base unit or place an extender from the outlet connector to the unit itself.
- 6. Continuous Suction device provided by manufacturer cannot be placed on base unit when aircraft seats are in place on C-21's. To have enough room for securing the suction device on the base unit requires placement between the C-21 aircraft seats.

SUMMARY

The Lifeport, Inc., Patient Loading Utility System was modified to pass environmental extremes and is considered approved for use. It operates within expected parameters when subjected to simulated cabin altitude's and does not produce a hazard to patient or crew during rapid decompression. However, there are several human factor concerns that should be addressed prior to use in USAF aeromedical evacuation missions. See Recommendations this report.

REFERENCES

- 1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
- 2. AFI 41-203, Electrical Shock Hazards
- 3. AFI 41-201, Equipment Management in Hospitals
- 4. MIL-STD 1472, <u>Human Engineering Design Criteria for Military Systems</u>, <u>Equipment</u>, and <u>Facilities</u>.
- 5. Emergency Care Research Institute (ECRI)
- 6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
- 7. MIL-STD 461D, <u>Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.</u>
- 8. MIL-STD-462 D, Measurement of EMI Characteristics.
- 9. IMPACT Instrumentation Inc., IMPACT 308ME13, Operations & Service Manual.
- 10. <u>Aeromedical Research Procedures Guide</u>, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

APPENDIX MANUFACTURER'S SPECIFICATIONS OF THE LIFEPORT, INC. PATIENT LOADING UTILITY SYSTEM (PLUS)

Model: Patient Loading Utility System (PLUS)

Manufacturer: LifePort, Inc.

12808 N.E. 95th Street Vancouver, WA 98682

1-800-854-8524

Bench Length:

72"

(182.88 cm)

Width:

17"

(43.25 cm)

Height:

10"

(25.40 cm) to top of bench

Standard Unit Weight:

118 lbs.

(53.1 kgs)

Air Pump Capacity:

22 lpm @ 50 psi

Vacuum Pump Capacity:

19 lpm @ 22 in.Hg.

Inverter:

(2) 518 watt to provide 4.3 amps of 115 VAC/60 Hz power

Oxygen Supply:

3,500 L.

Control Panel:

Provides Oxygen, Medical Air, Vacuum and 115 VAC/60 Hz

outlets

AeroSled Transport System: Pneumatically controlled backrest that adjusts from 0-60° to include a patient safety restraint system, and a high density foam

pad and cover

Patient Loading System:

Attaches to the EUT or a ramp bay and folds for storage

AeroSled Arch:

Used to mount life support equipment. Mounts over AeroSled

Transport System

I.V. Pole:

Telescopes and has two hooks for multiple I.V. bags